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Applicant: Carter, *et al.*

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For: "MATERIALS AND METHODS FOR
IMPROVED BONE TENDON BONE
TRANSPLANTATION"

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Group Art Unit: 3738

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Examiner: Alvin Stewart

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RESPONSE UNDER 37 CFR § 1.116

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Sir:

REMARKS

In response to the Final Official Action of November 18, 2003, for which a response was due January 18, 2004, now extended one (1) month to February 18, 2004, Applicants respectfully request that the Examiner exercise his discretion under and consider the following response filed under § 1.116

It is respectfully submitted that the Patent Office erred in rejecting claims 1, 2, 4, 5, and 19-24 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,067,962 ("Campbell") in view of U.S. Patent No. 5,092,887 ("Gendler") because, as pointed out below, the references, either alone or in combination, do not teach or suggest each element of the claimed invention. Moreover, Gendler "teaches away."

I. The Rejection under 35 U.S.C. § 103(a) over Campbell in view of Gendler is Legally Erroneous

Claims 1, 2, 4, 5, and 19-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,067,962 (“Campbell”) in view of U.S. Patent No. 5,092,887 (“Gendler”). Independent claim 1, as previously amended, is drawn to a unitary, implantable bone-tendon-bone allograft, wherein the allograft comprises at least one bone block and a tendon **naturally occurring thereon**, wherein the block is shaped into a dowel or a dowel that has a tapered region. Dependent claim 2 is directed to allografts made from specific tendons, dependent claim 4 to an allograft further comprising a groove for a fixation screw, and claim 5 to an allograft further comprising graft manipulation holes. Claims 19-24 are similarly drawn to an allograft utilizing a naturally occurring attachment (claim 19), an allograft of claim 19 with a dowel shape (claim 20) and a tapered shape (claim 21), an allograft of claim 19 derived from a patella (Claim 22) and from a tibia (claim 23), and an allograft of claim 23 processed to minimize pathogenic or antigenic agents.

The Patent Office contends that Campbell discloses a naturally occurring bone-to-ligament-to-bone attachment comprising two bone blocks shaped into a dowel that has a tapered shape. However, the examiner acknowledges that the harvested ligament comes from a bovine ligament and is **not** an allograft. The Examiner contends that the claims are unpatentable in light of Gendler, alleging that Gendler discloses a naturally occurring bone-to-ligament attachment comprising two bone blocks attached by a ligament, including autografts, allografts, or xenografts. Regarding claim 4, the Examiner contends that the grooves are inherently formed when an interface screw digs the bone during implantation. Regarding claim 5, the Examiner cites Figure 3 of Campbell. Finally, with regards to claim 24, the Examiner cites col. 3, lines 37-45 of Campbell, which recite chemical processing of the xenograft. The Applicants’ respectfully disagree with these alleged grounds for rejection.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of a claim’s limitations. See MPEP § 2142, 2143, and 2143.03 and *In re Vaeck*, 20 USPQ2d 1438

(Fed. Cir. 1991). However, neither Campbell nor Gendler, alone or in combination, disclose an **allograft** bone-tendon-bone graft useful in orthopedic surgery comprising one or more bone blocks and a tendon attached by a **naturally occurring tendon-to-bone attachment** to the bone blocks.

Campbell teaches only the use of **xenograft** bone-tendon-bone grafts and nowhere mentions the possibility of **allografts** or **autografts**. Gendler, meanwhile, does not even teach the use of bone blocks, much less a naturally occurring bone-tendon-bone attachment. Gendler teaches the use of artificial ligaments and tendons and only generally discloses allograft and autograft replacement grafts. Gendler does mention the term “natural,” but only in the context of natural **repair**, *i.e.*, aiding the patient’s own natural tendon repair process through artificially supporting the joint; **not** by employing an implant comprising a **naturally occurring bone-tendon-bone attachment**, which itself will be the replacement tendon. In fact, Gendler teaches away from the use of non-artificial replacement grafts, finding problems with both “autografts” and “xenografts.” See Gendler col. 3, lines 55-62 (“A problem associated with the autogenous transplant methods for ligament reconstruction relates to damage and loss of strength of the donor structure...These procedures are accompanied by long rehabilitation regimens.”); also Gendler at col. 1, lines 33-36 (“Xenografts have tended to be unpredictable in the long term for restoring full strength and stability to the involved joint.”).

Thus, given Gendler’s **teaching away**, there is no motivation or suggestion to one skilled in the art to combine the xenografts of Campbell with the problematic autografts or xenografts discussed in Gendler. See *In re Dembiczaik*, 175 F.3d 994, 999 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); also See *In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) (“error to find obviousness where references ‘diverge from and teach away from the invention at hand’”) *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983).

Additionally, even absent the above reasons for allowance, Applicants respectfully disagree with the Patent Office’s further argument regarding claim 4. Neither Campbell nor Gendler, either alone or in combination, discloses a fixation screw at all,

much less grooves cut into bone blocks to secure them. Campbell only discloses stainless steel pins for securing the bone blocks. As discussed above, Gendler does not disclose bone blocks at all. Even if Campbell or Gendler did disclose interference screws, however, Applicants respectfully disagree that grooves are inherently formed when an interference screw digs into a bone during implantation.

One can consider the analogy wherein cortical bone is hard like a hardwood (oak) and cancellous bone is softer and less dense like a softwood (pine). One can easily self-thread a screw in the softwood whereas it would be impossible to hand thread a screw in hardwood. Moreover, the hardwood would likely split from the effort. In hardwoods, one needs to drill a pilot hole first to accommodate the screw volume, whereby only the threads dig into the wood and hold the screw. In the field of bone grafts, cortical bone is hard and dense, like a hardwood. It is best to have a groove predrilled so as not to compress and possibly fracture the edges of the cortical bone both in the patient's leg and in the dowel at the end of the implant. As described in the specification, a groove offers more surface area for screw contact, and allows greater contact between the bone block and interior bone tunnel surfaces. [Specification at page 4, lines 11-16 ("To facilitate placement of a fixation screw, the dowels are preferably machined down the length of the bone block to form radius cuts 115, 125. The radius cuts 115, 125 aid in the attachment of the graft to recipient bone because they provide a groove to position a fixation screw, which results in **increased surface area at the contact** between the bone block and the screw. The radius cuts 115, 125 provide the additional advantage of **increasing the pull out loads** of the bone block. . . ."); emphasis added in bold.]

Additionally, regarding claim 5, Applicants further respectfully disagree that Campbell or Gendler, either alone or in combination, disclose graft manipulation holes. The disclosure of Campbell, meanwhile, makes it clear that holes 25 and 26 in Figure 3 are not graft manipulation holes, but rather are anchoring holes for holding pins. See Campbell, col. 3, lines 28-33 ("First and second holes 25 and 26 may be machined in the first and second bone plugs 23 and 24 for use in anchoring the bone plugs 23 and 24 in place, such as by pinning as subsequently described..."). Campbell does not disclose that these holes would be suitable for use as graft manipulation holes. Specifically, Campbell does not disclose that the anchoring pin holes are of suitable size or shape to receive graft

manipulation tools or sutures. Gendler fails to disclose any bone blocks at all and thus, could not disclose or suggest the Applicants' bone blocks of claim 5 having "manipulation holes.

For the foregoing reasons, the rejection of claims 1, 2, 4, 5, and 19-24 under 35 U.S.C. §103(a) is legally erroneous. The Applicants respectfully request the withdrawal of this basis for rejection.

CONCLUSION

Claims 1, 2, 4, 5, and 19-24 stand finally rejected. In view of the arguments provided herein, all bases for rejecting claims 1, 2, 4, 5, and 19-24, under 35 U.S.C. § 103(a) for alleged obviousness have been rebutted. The allowance of claims 1, 2, 4, 5, and 19-24 is respectfully requested.

Respectfully submitted,

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